(5)

No. 95-1900

Supreme Court, U.S.
FILED
MAY 29 1996
CLERK

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1995

EXXON CHEMICAL PATENTS, INC., EXXON CORPORATION, AND EXXON RESEARCH AND ENGINEERING COMPANY,

*Petitioners,*

—v.—

LUBRIZOL CORPORATION,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

John C. Vassil*
M. Caragh Noone
Richard Straussman
Alana G. Firester
MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
*Attorneys for Amicus Curiae, Pharmaceutical Research and Manufacturers of America*

* *Counsel of Record*

23pp

## QUESTION PRESENTED

PhRMA concurs in the first question presented in the petition for a writ of certiorari. For convenience, that question is:

> 1. Whether the court of appeals erred in holding, contrary to the law upon which many thousands of patents are based, that patents for chemical composition products cannot be claimed solely by identifying the ingredients used to make the composition?

## TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES ..... iv

INTEREST OF AMICUS CURIAE ..... 1

SUMMARY OF ARGUMENT ..... 1

ARGUMENT ..... 2

A. Introduction ..... 2

B. The Federal Circuit's Ruling Is Contrary To Well Established Law Relied Upon By The Pharmaceutical Industry ..... 4

1. The Federal Circuit's Ruling ..... 4

2. The Federal Circuit's Ruling Is Contrary to Established Patent Law ..... 5

C. The Federal Circuit's Decision Jeopardizes The Validity Of Numerous Pharmaceutical Patents ..... 8

D. The Federal Circuit's Ruling Will In Some Cases Make Proof Of Infringement Of An Ingredient-Based Pharmaceutical Composition Claim Virtually Impossible ..... 11

E. Utilization Of Product-By-Process Claims Is Not A Viable Alternative ..... 13

PAGE

F. The Uncertainty Created By The Federal Circuit's Ruling Is Inconsistent With The Objectives Sought When That Court Was Formed ..... 14

CONCLUSION ..... 15

## TABLE OF AUTHORITIES

**Cases** PAGE

*American Chem. Paint Co. v. Firestone Steel Prods., Co.*, 117 F.2d 927 (6th Cir. 1941) ..... 11

*Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992) ..... 13

*Deep Welding, Inc. v. Sciaky Bros., Inc.*, 417 F.2d 1227 (7th Cir. 1969), *cert. denied*, 397 U.S. 1037 (1970) ..... 7

*Diamond Rubber Co. v. Consolidated Tire Co.*, 220 U.S. 428 (1911) ..... 7

*Eames v. Andrews*, 122 U.S. 40 (1887) ..... 7

*Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1533 (Fed. Cir. 1995), *reh'g denied*, 77 F.3d 450 (Fed. Cir. 1996) ..... 1-7, 12-13

*Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983) ..... 7

*Giant Powder Co. v. California Powder Works*, 98 U.S. 126 (1878) ..... 14

*Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928) ..... 5

*Markman v. Westview Instruments, Inc.*, 116 S.Ct. 1384 (1996) ..... 14-15

*Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989) .... 8

*In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963)..... 14

*PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558 (Fed. Cir. 1996) ..... 8

PAGE

*Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) ..... 13

*Smithkline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878 (Fed. Cir. 1988) ..... 12

*Van Epps v. United Box Board & Paper Co.*, 143 F. 869 (2d Cir.), *cert. denied*, 202 U.S. 617 (1906) . 7

**Rules and Statutes**

35 U.S.C. § 112 .....7-9

**Other Authorities**

*Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 Jurimetrics J. 295 (1994) .....3-4

D. Green, *Big Increase In World Drug Sales*, The Financial Times Ltd. (Jan. 22, 1996) ..... 3

*Global Competitiveness of U.S. Advanced Technology Mfg. Indus.: Pharmaceuticals*, U.S.I.T. Comm'n. No. 332-302 (1991) ..... 3

H.R. Rep. No. 312, 97th Cong., 1st Sess. (1981)..... 14

Hearings Before the Oversight and Investigations Subcommittee of the House Commerce Comm. (May 25, 1995) (Prepared Statement of Gordon M. Binder, Chairman and Chief Executive Officer Amgen) ..... 4

J.A. DiMasi, *Trends in Drug Development Costs, Times and Risks*, 29 Drug Info. J. 376 (1995) .... 3

PAGE

K. Kaitin et al., *The Role of Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. Clinical Pharmacology 412 (1993) ..... 3

Manual of Patent Examining Procedure, § 2113 (U.S. Pat. & Trademark Office 1995)..... 14

Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting*, § 49 (3d ed. 1990) ..... 5

## INDEX OF LODGING

**APPENDIX A** U.S. Patent No. 4,046,879

**APPENDIX B** U.S. Patent No. 3,937,825

## INTEREST OF AMICUS CURIAE

PhRMA is a voluntary, nonprofit association representing approximately eighty-five research-based pharmaceutical and biotechnology companies. PhRMA members research and develop over 90 percent of all new prescription medicines. In doing so, PhRMA members commit over $15 billion annually to pharmaceutical and medical research. The decision below, if not reversed, may affect the willingness of the industry to risk investment in research by casting a shadow over the validity of numerous unexpired patents and rendering them, as a practical matter, unenforceable against infringers because of difficulties in proving infringement.

PhRMA has reviewed the petition for a writ of certiorari filed by Petitioners and concurs in the substance thereof. However, PhRMA wishes to call certain additional matters to the Court's attention. The instant brief provides a discussion of the serious consequences that will result from the decision of the United States Court of Appeals for the Federal Circuit in *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1533 (Fed. Cir. 1995), *reh'g denied*, 77 F.3d 450 (Fed. Cir. 1996) unless review is granted. PhRMA respectfully requests that in deciding whether to grant certiorari in this matter, the Court consider the additional perspective of the pharmaceutical industry's trade association.

All parties have consented to the filing of this brief. The letters of consent have been filed with the Court.

## SUMMARY OF ARGUMENT

Exxon's petition for a writ of certiorari should be granted because the Federal Circuit's ruling is contrary to well established patent law. In *Exxon*, the Federal Circuit held that to establish infringement Exxon was required to prove that *after* combination, for at least some period of time, none of the ingredients used by Lubrizol to make the accused product

interacted such that their form or amount changed from that claimed in Exxon's patent. This decision contradicts well established law regarding claim drafting and interpretation. The Federal Circuit's decision casts a shadow upon the validity and enforceability of a multitude of pharmaceutical composition patents. The uncertainty this decision creates regarding the enforcement and validity of a large number of unexpired patents runs afoul of one of the central purposes of the Federal Circuit: to apply the patent laws in a predictable and uniform manner.

## ARGUMENT

### A. Introduction

Two compelling reasons support granting certiorari in this case. First, the claim construction of Exxon's ingredient-based composition claim[1] adopted by the Federal Circuit, which was not advanced by either party, is, in the words of Judge Newman, a Ph.D. in chemistry with industry experience as both a research chemist and a patent practitioner, "incorrect as a matter of law, as a matter of chemistry, and as a matter of patent practice." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 77 F.3d 450, 451 (Fed. Cir. 1996) (Newman, J. dissenting from denial of rehearing *en banc*). Second, the Federal Circuit's construction of ingredient-based claims potentially invalidates thousands of unexpired patents, creating a "massive taint upon existing property rights." *Id.* at 453.

This "taint" upon existing patents impacts the pharmaceutical industry and all other industries in which novel and use-

---

[1] The phrase "ingredient-based composition claim" refers to patent claims which claim a composition by listing the ingredients used in making it. In many cases the claim also specifies the amount or ratio of the ingredients.

ful compositions are claimed using the standard, ingredient-based method of claiming inventions.[2]

Pharmaceutical manufacturers spend billions of dollars each year to develop new pharmaceuticals. D. Green, *Big Increase In World Drug Sales*, The Financial Times Ltd. (Jan. 22, 1996). Indeed, they are responsible for developing over 90 percent of FDA approved drugs. K. Kaitin et al., *The Role of Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. Clinical Pharmacology 412, 413 (1993). However, bringing a single drug to market takes an average of twelve years and costs approximately $350 million. J.A. DiMasi, *Trends in Drug Development Costs, Times and Risks*, 29 Drug Info. J. 376 (1995). Moreover, commercially marketable drugs result from only approximately one out of every 4,000 discovered compounds. *Global Competitiveness of U.S. Advanced Technology Mfg. Indus.: Pharmaceuticals*, U.S.I.T. Comm'n. No. 332-302, 4-18 (1991). This low yield requires the pharmaceutical industry to recoup its enormous research and development expenditures by sales of the approved products. *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 Jurimetrics J. 295, 303 (1994). Consequently, the enforceability of patents on approved products is critical to

---

[2] As Judge Newman noted in her dissent from the denial of the rehearing *en banc*, a large number of industries rely heavily on this method of claiming. Indeed, she explained that of 608 "chemical" patents listed in the December 26, 1995 Official Gazette of the Patent and Trademark Office, about 100 claimed compositions by listing their ingredients. These claims were directed to inventions as varied as "a pollution control composition, a dye transfer inhibiting composition, a shampoo composition, a paint stripper composition, a polyol composition for polyurethane foams, a cold water detergent composition, a granular detergent composition, a wood preservative, an adhesive composition, photosensitive and radiation-sensitive resin composition, an x-ray film developer composition, a radiation-absorbing glass composition, and many more". *Exxon*, 77 F.3d at 454 (Newman, J., dissenting from denial of reh'g *en banc*).

each pharmaceutical company's survival and incentive for further innovation. *Id.* at 304.[3]

## B. The Federal Circuit's Ruling Is Contrary To Well Established Law Relied Upon By The Pharmaceutical Industry

### 1. The Federal Circuit's Ruling

The Exxon patent claims a chemical composition by reciting the amount of each ingredient used to make the composition. At trial Exxon (and the trial court) interpreted the claim to include all compositions made from the ingredients identified in the patent claim in the amounts specified. The trial court rejected Lubrizol's interpretation, which would have limited the claim to "final" products that contained the claimed ingredients in the claimed form and amount.

The Federal Circuit rejected the claim constructions advanced by both Exxon and Lubrizol and adopted its own novel interpretation, requiring proof of the presence of the claimed ingredients in their claimed amounts at any time after combination. *Exxon*, 64 F.3d at 1560. Thus, the Federal Circuit held that there is no infringement where any ingredient interacts with another such that the ingredient changes in chemical form or amount from that listed in the claim. As Judge Newman noted "any chemical change or interaction within the composition, even loose 'complexing' as appears to happen between ingredients of this composition, renders

---

[3] The U.S. Department of Commerce estimates that the pharmaceutical industry will contribute more than $50 billion of sales to the economy by the end of this decade. *See* Hearings Before the Oversight and Investigations Subcommittee of the House Commerce Comm. (May 25, 1995) (Prepared Statement of Gordon M. Binder, Chairman and Chief Executive Officer, Amgen Corporation). These companies cannot continue this immense research effort absent the protection afforded by valid patents that can be enforced against an infringer by proving use of the constituents identified in the patent claim.

the claim useless." *Exxon*, 77 F.3d at 452 (Newman, J., dissenting from denial of reh'g *en banc*).

### 2. The Federal Circuit's Ruling Is Contrary to Established Patent Law

It is a well established principle of patent law that chemical compositions, such as pharmaceuticals, may be claimed by reciting the ingredients used to make the composition. In *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), this Court recognized that "a patent of a composition of matter, should contain some description of the ingredients entering into the composition which would both define the patent, and carry it beyond the previous development of the art." *Holland Furniture Co.*, 277 U.S. at 254 (citations omitted). Moreover, patent treatises universally recognize that compositions are generally claimed by the list of ingredients used to make the composition. *See, e.g.* Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting*, § 49, at 148 (3d ed. 1990) ("Composition of matter claims *list the chemical ingredients (compounds, elements or radicals) making up the composition or compound*. . . . Where necessary to novelty, etc., the proportions or other conditions or parameters of the compound are stated, usually in ranges of concentration of ingredients.") (emphasis added).

Although the *Exxon* decision may impact the chemical and petroleum industries to a greater extent than the pharmaceutical industry, patents for pharmaceuticals have routinely been sought using ingredient-based claims. A survey of pharmaceutical patents[4] issued over the past six months revealed that more than 200 patents contain ingredient-based composition claims reciting a single active ingredient and an inert carrier or diluent. At least 31 of these patents contain ingredient-based composition claims reciting three or more ingredients.

---

[4] Classes 424 and 514, entitled "Drug, Bio-Affecting and Body Treating Compositions," were searched.

Use of this claiming format is often necessary given the complex nature of the chemicals that comprise pharmaceutical compositions. A pharmaceutical is seldom administered alone, but is almost always a mixture of one or more active ingredients and at least one other substance. In the simplest case, a pharmaceutical will consist of an active ingredient and an excipient or inert carrier. Although the carrier is termed "inert," this simply means it does not interfere with the therapeutic effect of the active ingredient.

In a more complex situation, a patented pharmaceutical may consist of an active ingredient combined with several other ingredients, which increase absorption or otherwise enhance the beneficial effect of the active ingredient. Generally, such a composition is claimed by reciting the ingredients in the ratios used to make the composition. A patentee does not usually test for the chemical and physical interactions that occur upon mixing the ingredients, other than to ascertain that the post-combination composition is safe, effective and meets the Food and Drug Administration requirements. Indeed, where a number of different ingredients are added to the active ingredient, elucidation of the myriad chemical and physical interactions that occur between the combined ingredients may be impossible, and is rarely available at the time the patent application is filed.

Similarly, where the pharmaceutical consists of a mixture of two or more active ingredients which yield a synergistic effect when combined, the patentee may not entirely understand the precise chemical or physical interactions that occur to yield the unexpectedly good results. In each of these situations, claiming the composition by the ingredients and their amounts is, as Judge Newman recognized, "the clearest, most accurate, and most comprehensible way of describing such inventions." *Exxon*, 77 F.3d at 453. (Newman, J., dissenting from denial of reh'g *en banc*).[5]

---

[5] Because those skilled in the art understand the claims to recite a product that may be reproduced by combining the listed ingredients, the

Moreover, use of ingredient-based composition claims is in accordance with the long-standing rule that "where a patent discloses means by which a novel and successful result is secured, it is immaterial whether the patentee understands or correctly states the theory or philosophical principles of the mechanics which produces the new result." *Van Epps v. United Box Board & Paper Co.*, 143 F. 869, 872 (2d Cir.), *cert. denied*, 202 U.S. 617 (1906); *Deep Welding, Inc. v. Sciaky Bros., Inc.*, 417 F.2d 1227, 1239 (7th Cir. 1969), *cert. denied*, 397 U.S. 1037 (1970). As this Court explained:

> An inventor may be ignorant of the scientific principle, or he may think he knows it and yet be uncertain, or he may be confident as to what it is and others may think differently. All this is immaterial, if by the specification the thing to be done is so set forth that it can be reproduced.

*Eames v. Andrews*, 122 U.S. 40, 56 (1887). *See also Diamond Rubber Co. v. Consolidated Tire Co.*, 220 U.S. 428, 435-36 (1911) ("It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative ideas involved."); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983) ("[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.").

The Federal Circuit's *de novo* claim construction in *Exxon* inherently violates these long standing principles of law. Under the Federal Circuit's construction, an ingredient-based

---

composition is adequately described and enabled as required by 35 U.S.C. § 112. As Judge Newman explained:

> When the invention is adequately described and claimed by listing the ingredients of the composition, and is understood by persons of skill in the field of the invention, the law demands no more.

*Exxon*, 77 F.3d at 452. (Newman, J., dissenting from denial of reh'g *en banc*)

composition claim is not infringed if a chemical reaction or a physical interaction results in a change in the form or amount of the ingredients after mixing. Thus, to establish infringement under the Federal Circuit's interpretation of these claims, a pharmaceutical patentee must not only understand, but be able to prove the nature and timing of the multitude of physical and chemical interactions that occur among the various ingredients after mixing. Clearly, this requirement violates even the Federal Circuit's own statement in *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) that "it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works."

### C. The Federal Circuit's Decision Jeopardizes The Validity Of Numerous Pharmaceutical Patents

Although in *Exxon* the Federal Circuit reversed a judgment of infringement, the rationale of the decision can extend to, and jeopardize, the validity of numerous pharmaceutical composition patent claims. Specifically, by requiring that the post-combination composition contain each of the recited ingredients in the specified amounts, the Federal Circuit potentially invalidates numerous existing ingredient- based claims for lack of enablement under 35 U.S.C. § 112.

35 U.S.C. § 112 states, in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .

35 U.S.C. § 112, ¶1 (1996). Thus, to satisfy § 112, the specification must disclose how to make and use the claimed invention. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996). Prior to the Federal Circuit's decision in *Exxon*, U.S. inventors, patent attorneys and patent

examiners understood ingredient-based pharmaceutical composition claims to include any composition that resulted from the mixing of the recited ingredients in the specified amounts. As long as the specification taught how to make the claimed composition (*e.g.*, by mixing the described ingredients in the described amounts) and use the resulting composition, the requirements of § 112 were met.

Under the Federal Circuit's new claim construction, however, the claimed invention is a post-combination product that contains the recited ingredients in the listed amounts. Consequently, to comply with 35 U.S.C. § 112, the specification must describe how to make and use this post-combination product. Specifically, the specification must disclose how to make a product that contains, *after* combination, the listed ingredients in the listed amounts, or, at a minimum, describes the chemical and physical interactions that occur between the various ingredients after they are mixed.

In many cases, the specifications of pharmaceutical patents containing ingredient-based claims do not address or describe the composition of the post-combination product or the interaction of the various ingredients upon mixing.

For example,[6] in U.S. Patent No. 4,046,879, issued Sept. 6, 1972, which claims a topical antiviral composition by reciting the ingredients,[7] the specification is silent regarding the chemical composition of the post-combination product.

---

[6] To avoid casting aspersions upon patents currently in effect, the examples discussed herein are limited to expired patents. However, pharmaceutical compositions are currently claimed using the ingredient-based approach. Indeed, as discussed *supra*, at least 200 "pharmaceutical" patents containing claims of this type have issued in the past six months.

[7] Claim 1, which is representative, states:

> 1. A topical antiviral pharmaceutical composition consisting essentially of an inert carrier and uniformly distributed therein 0.05 to 20 mgm of at least one complex-former for bi-valent cations per gram of total weight of said composition.

*See* Appendix A.[8] Additionally, the chemical and physical interactions that occur between the ingredients after mixing are not discussed. *Id.* However, after the Federal Circuit's ruling in *Exxon*, this claim, were it still in effect, would be construed to claim a post-combination composition containing each of the recited ingredients in an amount within the recited range. It is not clear that the specification would be viewed as sufficient to describe or enable this post-combination composition. Thus, this patent would potentially be invalid under the Federal Circuit's construction of ingredient-based claims in *Exxon*.

Similarly, U.S. Patent No. 3,937,825, issued Feb. 10, 1976, claims an anthelmintic composition by reciting its ingredients.[9] *See* Appendix B.[10] The specification provides a detailed

---

[8] Appendices A and B, U.S. Patent Nos. 4,046,879 and 3,937,825 respectively, are contained in Lodging of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of Petition for a Writ of Certiorari, filed with the instant brief. These patent documents could not be legibly reproduced as a booklet-format appendix. Thus, they were filed as a lodging.

[9] Claim 1 recites:

> 1. An anthelmintic composition for controlling strongyles in equine species comprising O,O dimethyl (2,2,2 trichloro-1-hydroxyethyl) phosphonate and 1-6- phenyl 2,3,5,6-tetrahydroimidazo [2,1-b] thiazole hydrochloride in a amount of from 4 grams to about 40 grams in a weight ratio of 5 parts by weight of O,O-dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate to each part by weight of 1-6-phenyl-2,3,5,6-tetrahydroimidazo [2,1-b]-thiazole thiazole [sic] hydrochloride.

The specification states that the composition may include other ingredients including "solid or liquid adjuvants or formulation aids" (col. 2, lines 33-34), "tableting ingredients such as corn starch, lactose, sucrose, sorbitol, talc, stearic acid, magnesium stearate, dicalcium phosphate, gums or similar materials" (col. 2, lines 65-68), flavored emulsions with edible oils, elixirs sterile suspensions (col. 3, lines 22-26) and other diluents, carriers or vehicles (col. 3, lines 34-35).

[10] Appendix B is contained in Lodging of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of Petition for a Writ of Certiorari, filed with the instant brief.

description of how the claimed composition is prepared from the recited ingredients and used to treat parasites in horses. However, the specification is silent regarding the characteristics of the post-combination composition and the nature of the chemical and physical interactions between the ingredients upon combination. Thus, this patent too would potentially be invalidated under the Federal Circuit's interpretation of ingredient-based claims in *Exxon*.

These are but two examples of hundreds, if not thousands, of pharmaceutical patents whose validity may be jeopardized by the Federal Circuit's ruling in *Exxon*. Moreover, it should be noted that in many of these cases the information necessary to enable the claims, as construed by the Federal Circuit, is completely unavailable because the inventors do not, and in certain instances cannot, understand the post-combination interaction of the complex chemical ingredients.

### D. The Federal Circuit's Ruling Will In Some Cases Make Proof Of Infringement Of An Ingredient-Based Pharmaceutical Composition Claim Virtually Impossible

Assuming that an ingredient-based composition claim remains valid under the Federal Circuit's construction in *Exxon*, it may still be rendered essentially unenforceable by the often insurmountable problems this ruling creates in proving infringement.

Prior to the *Exxon* decision, a pharmaceutical patentee with an ingredient-based claim could establish infringement simply by proving that the accused composition was made using the recited ingredients in the specified amounts. *See, e.g., American Chem. Paint Co. v. Firestone Steel Prods., Co.*, 117 F.2d 927, 930-31 (6th Cir. 1941) ("Questions of infringement of patents for compositions of matter are peculiar to themselves. Infringement depends upon the identity or equivalence of the ingredients and upon substantial sameness of the proportions in which the ingredients are used."). However, under

the Federal Circuit's new interpretation of ingredient-based claims, the patentee must prove that the product that results from combination of the ingredients contains the recited ingredients in the specified amounts. Consequently, infringement can only be established if the patentee can prove that *after* mixing the ingredients remain in their pre-combination states and amounts for some period of time.

This ruling places a significant burden on the patentee, who bears the burden of establishing infringement. *Smithkline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). As discussed *supra*, sections B & C, in many situations a pharmaceutical patentee does not know what happens to the complex chemical ingredients after they are combined. Moreover, the onus that the Federal Circuit's construction places on the patentee is increased where, due to technological limitations, the patentee *cannot* ascertain the precise interactions between the ingredients or the complex chemistry of the post-combination product. In these situations, proof of infringement will be virtually impossible,[11] leaving, in Judge Newman's words, "a useless patent that can not be enforced against the identical composition made from the identical ingredients in the identical ratios." *Exxon*, 77 F.3d at 454 (Newman, J., dissenting from denial of reh'g *en banc*).

---

[11] It should be noted that in certain circumstances, even where the nature and type of reactions between the ingredients are understood, infringement may be impossible to prove. For example, if the reaction, which changes the form or amount of one or more ingredients, occurs virtually instantaneously, or occurs at different rates and to different extents depending on the conditions of combination, use or storage, a patentee may be unable to meet his burden of establishing infringement although the accused infringer uses the recited ingredients to make an identical product.

### E. Utilization Of Product-By-Process Claims Is Not A Viable Alternative

Ignoring the fact that an ingredient-based claim, like Exxon's, "is neither a process nor a product, but a mixture of ingredients to form a composition," *Exxon*, 77 F.3d at 456 n.3 (Newman, J., dissenting from denial of reh'g *en banc*), the Federal Circuit majority suggests that patentees should draft product-by-process claims rather than ingredient-based composition claims. *See Exxon*, 64 F.3d at 1563 (Plager, J., concurring). However, this is not a viable alternative to ingredient-based composition claims.

As an initial matter, this advice does nothing to remove the shadow the Federal Circuit's ruling casts over the numerous pharmaceutical patents already in existence, which contain ingredient-based claims.

Moreover, even if one were to assume an ingredient list is a process and could properly be claimed in a product-by-process format, in light of the present conflict in Federal Circuit holdings regarding product-by-process claims, there is considerable uncertainty as to their viability and how courts should and will construe them. *Compare Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."), *with*, *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 846-47 (Fed. Cir. 1992) ("Thus, process terms in product-by-process claims serve as limitations in determining infringement."). Thus, it is not clear that use of a product-by-process format offers the same scope of protection as a composition claim. Indeed, as the Court of Customs and Patent Appeals noted, "[composition] claims have well-recognized advantages to those in the business of making and selling compounds, in contrast to process-of-use claims, because

competitors in the sale of compounds are not generally users." *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963).[12]

In short, product-by-process claims do not provide pharmaceutical patentees with an acceptable alternative to the traditional, ingredient-based composition claim format, particularly given this Court's recognition that invention of compounds or mixtures may have no connection with the process for making them. *Giant Powder Co. v. California Powder Works*, 98 U.S. 126, 137 (1878).

### F. The Uncertainty Created By The Federal Circuit's Ruling Is Inconsistent With The Objectives Sought When That Court Was Formed

As explained, *supra*, the Federal Circuit's ruling in *Exxon* creates significant uncertainties in the pharmaceutical and other industries because patentees no longer know how their claims will be construed or how (or if) infringement may be established. This uncertainty is contrary to and essentially nullifies one of Congress' main objectives in establishing the Federal Circuit: creation of certainty and uniformity in application of the patent laws. *See, e.g.*, H.R. Rep. No. 312, 97th Cong., 1st Sess., at 20-33 (1981) ("The new Court of Appeals for the Federal Circuit will provide nationwide uniformity in patent law, will make the rules applied in patent litigation more predictable and will eliminate . . . forum-shopping . . ."). Indeed, as this Court noted in *Markman v Westview Instruments, Inc.*:

> It was just for the sake of such desirable uniformity that Congress created the Court of Appeals for the Federal

---

[12] Additionally, product-by-process claims are not favored by the Patent Trademark Office because of the uncertainties and burden involved in examining them. *See* Manual of Patent Examining Procedure § 2113, at 2100-31 (U.S. Pat. & Trademark Office 1995) ("As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." (citations omitted)).

> Circuit as an exclusive appellate court for patent cases, observing that increased uniformity would "strengthen the United States patent system in such a way as to foster technological growth and industrial innovation."

*Markman*, 116 S.Ct. 1384, 1396 (1996) (citations omitted).

## CONCLUSION

For the foregoing reasons, and those set forth by the Petitioners, *amicus curiae* PhRMA respectfully urges the Court to grant the petition for a writ of certiorari.

Respectfully submitted,

John C. Vassil*
M. Caragh Noone
Richard Straussman
Alana G. Firester
MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154
(212) 758-8519

*Attorneys for Amicus Curiae, Pharmaceutical Research and Manufacturers of America.*

* *Counsel of Record*